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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,664	01/26/2004	Leonard S. Girsh	GIR-105CXC1	9812

23557 7590 01/11/2008

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1656	
MAIL DATE	**DELIVERY MODE**
01/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,664	GIRSH, LEONARD S.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of garlic as the compound generally accepted as safe added to the anabolic composition and soy lecithin as a material of component, in the response to restriction requirement and amendment filed November 8, 2007 is acknowledged. In the amendment, claims 1, 2 and 7 have been amended. Therefore, claims 1-8 are examined.

Priority

2. The parent application of the instant application, 09/639,859, filed 8/16/2000, does not disclose the surfactant component such as Tween 80, SPAN 80, grape seed extract or grape extract in the anabolic composition, while the parent application, 10/752,298, filed 1/5/2004 discloses all the components in the anabolic composition, thus the priority date for claim 1 is 1/5/2004.

Abstract

3. Applicant is reminded of the proper content of an abstract of the disclosure. A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the

abstract should mention by way of example the preferred modification or alternative. The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Claim Objections

4. Claims 2 and 7 are objected to because the claim contains non-elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-8 are directed to an anabolic composition comprising at least one glycosaminoglycan, proteoglycan aggregate complex; about 1 to 3 grams of at least one polar surface lipid; a plurality of L-amino acids and glycine of about 9 to 25 grams in molar ratio of human tissue; a component of Polyoxyethylene Sorbitan Monooleate (TWEEN 80), Sorbitan monooleate (SPAN 80), grape seed extract, grape extract, and combinations thereof; and vitamins, minerals or trace elements.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

While the specification indicates that an anabolic composition can comprise three, four or five of the following components: Component #1 of 10-25 grams of molar ration amino acids of Neocate; Component #2 of polar surface active lipid, high HLB surfactant such as Tween 80 may be used along with Components #1 and #2; Component #3 of extracellular matrix such as a proteoglycan aggregate complex of chondroitin sulfate covalently bonded to core protein; Component #4 of vitamins, Minerals and trace elements; Component #5 comprising phytozyme, amylase or other components; Component #5 (the second #5) with addition pro-biotic component (pages 17-24), the specification does not disclose a genus of variants for a plurality of

L-amino acids and glycine in molar ratio of human tissue (part c), and a proteoglycan aggregate complex of protein and chondroitin (part a) in the anabolic composition. A single species of amino acid mixtures of Neocate (page 17, line 20-21; Example 3) and a disclosure of a proteoglycan aggregate complex of chondroitin sulfate covalently bonded to core protein (page 19, lines 29-31) does not provide sufficient description for the whole genus of a plurality of amino acids of any human tissue, or of a proteoglycan aggregate complex of protein and chondroitin, when there is substantial structural variation within the whole genus. For example, the specification does not describe the amino acid mixtures for various human tissues, nor identify various proteins in the proteoglycan aggregate complex of protein and chondroitin. The lack of description for the whole genus of a plurality of amino acids of human tissue, and of a proteoglycan aggregate complex of protein and chondroitin in the anabolic composition, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1-8 are indefinite because of the use of the term "at least one glycosaminoglycan, proteoglycan aggregate complex" or "plamalogen". The term cited renders the claim indefinite, it is unclear whether the term "at least one glycosaminoglycan, proteoglycan aggregate complex" means "at least one glycosaminoglycan or proteoglycan aggregate complex" or "at least one glycosaminoglycan and proteoglycan aggregate complex"; it is also not clear what the term "plamalogen" refers to. Claims 2-8 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

8. Claim 1 contains the trademark/trade name Tween 80 and SPAN 80. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a surfactant and, accordingly, the identification/description is indefinite.

9. Claim 6 is indefinite because of the use of the term "L-taurine" and "L-Carnitine". The terms cited renders the claim indefinite, it is unclear how a plurality of amino acids of a human tissue can contain "L-taurine" and "L-Carnitine", where taurine has the structure of H_2N-CH_2-CH_2-SO_3H and is not an L-amino acid, and "L-Carnitine" has the structure of Me_3N-CH_2-CH (OH)-CH_2-$CO2^-$ and is a non-natural amino acid.

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of co-pending application 11/501,380 (based on the elected claims filed 11/30/07; US 2007/0037777). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-8 in the instant application disclose an anabolic composition comprising at least one glycosaminoglycan, proteoglycan aggregate complex of extracellular matrix compound; about 1 to 3 grams of at least one polar surface lipid; a plurality of L-amino acids and glycine of about 9 to 25 grams in molar ratio of human tissue; a component of Polyoxyethylene Sorbitan Monooleate (TWEEN 80), Sorbitan monooleate (SPAN 80), grape seed extract, grape extract, and combinations thereof; and vitamins, minerals or trace elements; and the specification discloses a probiotic component can be included in the anabolic composition (page 23, lines 27-31), and the low HLB polar surface active lipid lipophilic surfactant PGPR can be used in the range of 0.01% to 0.05% to 10% (page 19, lines 7-22). This is obvious variation in view of

claims 1-12 of the co-pending application which disclose an anabolic composition comprising at least one amino acid, at least one extracellular matrix compound and at least one surfactant, wherein the concentration of surfactant in the composition is about 1% or greater with respect of total composition. Both sets of claims are directed to an anabolic composition comprising at least one amino acid, at least one extracellular matrix compound and at least one surfactant, wherein the concentration of surfactant in the composition can be about 1% or greater with respect of total composition. Thus, claims 1-8 in present application and claims 1-12 in the co-pending application are obvious variations of an anabolic composition comprising at least one amino acid, at least one extracellular matrix compound and at least one surfactant, wherein the concentration of surfactant in the composition can be about 1% or greater with respect of total composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of co-pending application 11/073,514 (US 2005/073,514). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-8 in the instant application disclose an anabolic composition comprising at least one glycosaminoglycan, proteoglycan aggregate complex of extracellular matrix compound; about 1 to 3 grams of at least one polar surface lipid; a plurality of L-amino acids and glycine of about 9 to 25 grams in molar ratio of human tissue; a component of Polyoxyethylene Sorbitan Monooleate (TWEEN 80), Sorbitan monooleate (SPAN 80), grape seed extract, grape extract, and combinations thereof; and

vitamins, minerals or trace elements; and the specification discloses a probiotic component can be included in the anabolic composition (page 23, lines 27-31). This is obvious variation in view of claims 1-9 of the co-pending application which disclose an anabolic composition comprising a first component comprising a plurality of L amino acids; a second component comprising at least one extracellular matrix compound; a third component comprising at least one polar surface active lipid; a fourth component comprising at least one vitamin, mineral or trace element; and a fifth component comprising a probiotic; the fourth and fifth components synergistically interacting with at least one of the first through third components to promote repair of damaged tissue. Both sets of claims are directed to an anabolic composition comprising a first component comprising a plurality of L amino acids; a second component comprising at least one extracellular matrix compound; a third component comprising at least one polar surface active lipid; a fourth component comprising at least one vitamin, mineral or trace element; and a fifth component comprising a probiotic may be included. Thus, claims 1-8 in present application and claims 1-9 in the co-pending application are obvious variations of an anabolic composition comprising a first component comprising a plurality of L amino acids; a second component comprising at least one extracellular matrix compound; a third component comprising at least one polar surface active lipid; a fourth component comprising at least one vitamin, mineral or trace element; and a fifth component comprising a probiotic may be included.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

CHIH-MIN KAM
PRIMARY EXAMINER

CMK
January 5, 2008